REMARKS

1. Amendments to the Sequence Listing

Enclosed herewith in full compliance with 37 C.F.R. §§1.821-1.825 is a Substitute Sequence Listing to be inserted into the specification as indicated above. The Substitute Sequence Listing in no way introduces new matter into the specification. Also submitted herewith in full compliance with 37 C.F.R. §§1.821-1.825 is an electronic copy of the Substitute Sequence Listing. The electronic copy of the Substitute Sequence Listing, file 2009_06_16_0147_0262PUS1_ST25.txt is identical to the paper copy, except that it lacks formatting. In no way do the paper copy nor the electronic copy of the Substitute Sequence Listing introduce new matter into the application.

The Sequence Listing is amended to list the YESP(K/R) motif sequences, which are found in the originally filed specification at page 12, lines 11-12. No new matter is introduced by these amendments.

2. Amendments to the Specification

The paragraph beginning on page 20, line 5, is replaced with a paragraph adding the SEQ ID NOs for the YESP(K/R) sequence.

Figure 10 and references to Figure 10 have been deleted. No new matter has been added.

3. Amendments to the Claims

Claim 65 has been amended to recite a "heterologous" polynucleotide. Support for this amendment is found in the Specification at page 54, line 5.

Claims 65, 100, and 101 have been amended to add the SEQ ID NOs for the YESP(K/R) sequence.

Claims 65, 67, and 102 have been amended to remove parentheses from around the SEQ ID NO.

No new matter has been added.

4. Interview Summary

Applicants sincerely thank Examiner Baum for granting their representatives the courtesy of an Interview. During the Interview on March 10, 2009 Applicants' representatives discussed the § 1.131/§1.132 Declarations submitted with the prior response, as well as the written description and enablement rejections. While no agreement was reached, Applicants again thank the Examiner for taking the time to participate in the Interview.

5. Objections to the Specification

Applicants have amended the Specification to remove Figure 10 and references to it. Applicants request that the objection be withdrawn.

6. Objections to the Claims

The Examiner objects to claims 65, 68, and 100-101 because the claims recite "amino acid sequence YESP(K/R)" but do not recite a SEQ ID NO. Applicants have amended the sequence listing to include the YESP(K/R) sequences. Applicants request that the rejection be withdrawn.

7. Claim Rejections under 35 U.S.C.§ 112, Indefiniteness

The Examiner rejects claims 65-66, 68-80, and 86-106 under 35 U.S.C. § 112, second paragraph, as being indefinite.

The Examiner states that in claim 65 it is unclear whether (SEQ ID NO: #) is intended to be a claim limitation. Applicants have amended the claims to recite only the SEQ ID NO. Applicants request that the rejection be withdrawn.

The Examiner indicates that the term "LpTFL1-like activity" found in claim 65 and other claims is unclear. As Applicants discuss below, LpTFL1-like activity is defined in the Specification.

(See page 4, lines 9-13). Based on this definition, one of skill in the art would understand the effect of the claimed nucleotides when expressed.

8. Claim Rejections under 35 U.S.C. § 112, Written Description

The Examiner rejects claims 65-66, 68-80, 86, and 88-100 under 35 U.S.C. § 112, first paragraph, as lacking sufficient written description. Applicants respectfully traverse.

The Examiner lays the legal foundation for the written description rejection by stating that:

> The Federal Circuit has recently clarified the application of the written description requirement to invention in the field of biotechnology. See *University of California v. Eli Lilly & Co.,* 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

(Office Action, page 5). Here, Applicants point out that the case cited by the Examiner as a "recent" clarification of the written description requirement was decided 10 years ago; and the Examiner's reliance on it fails to properly consider subsequent advances and developments in both the science and the law.

In particular, the Federal Circuit has, subsequent to the *Eli Lilly and Co.* decision, held that

> "the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science and technology, the predictability of the aspect at issue, and other considerations appropriate to subject matter. See, e.g., In re Wallach, 378 F.3d 1330, 1333-34 (Fed. Cir. 2004) (an amino acid sequence supports "the entire genus of DNA sequences" that can encode the amino acid sequence because "the state of the art has developed" such that it is a routine matter to convert one to the other)."

Capon, 418 F.3d at 1357 (Fed. Cir. 2005).

Moreover, the Federal Circuit has specifically said that "*Eli Lilly* does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must

always recite the gene or sequence, regardless of whether it is known in the prior art." *Falkner v. Inglis,* 79 USPQ2d 1001, 1008 (Fed. Cir. 2006).

Applicants submit that as required by the case law, they have provided a sufficient recitation of structural features common to members of the claimed genus, and that those features constitute a substantial portion of the genus. Moreover, Applicants submit that the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science and technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter, support Applicants' position that the claims are amply described.

a. Common structural features, which constitute a substantial portion of the genus.

Specifically, Applicants have described the genomic sequence in figure 2 (SEQ ID NO: 2), the cDNA sequence (SEQ ID NO: 1), and the protein sequence (SEQ ID NO: 3) (specification page 8, line 15 to page 9, line 12). Applicants describe the structure and function of the native promoter for the LpTFL1 gene in ryegrass. (Specification, *Id.*) Applicants have also presented preferred conservative replacements, which provide further guidance to one of skill the art. (Specification page 9, line 19 to page 10, line 3). With the claimed sequences being directed to 83% sequence identity to one of the specific SEQ ID NOs, a substantial portion of the genus of nucleic acids are explicitly described.

Furthermore, the Specification describes 11 amino acid residues in plant PEBP sequences which have been identified as essential for a functional protein. (Specification page 12, lines 4 - 12). In figure 5b, Applicants provide a consensus sequence between multiple members of the PEBP protein family. Figure 5b also denotes the 11 amino acid residues found to be essential for a functional protein using white arrowheads. (Specification page 25, line 17 - 22).

LpTFL1 differs from the consensus at only one position, namely amino acid residue 110. The inventors postulate that the serine residue at position 110 may confer the superior repressor

activity of the flowering demonstrated by LpTFL1. Thus, the described structure is related to the disclosed and claimed function.

The Specification provides multiple methods for isolating additional sequences which have this activity such as probing with the known sequence to find a sequence which selectively hybridizes to the known sequence, using recombinant DNA techniques and finding flanking DNA markers. (See specification page 16, line 19 to page 18, line 9). As these techniques are well known in the art, and based on the disclosure of the functional relationship to the structure, discussed above, one of skill would consider that Applicants had possession of the claimed genus at the time of filing.

Thus, one of skill would recognize that Applicants had possession of a genus of sequences having 83% sequence identity to SEQ ID NO: 1 or 2 and sequences having 83% sequence identity to a nucleotide sequence encoding SEQ ID NO: 3, which have the claimed activity of reducing or preventing flowering in a plant when expressed. Applicants request that the rejection be withdrawn.

b. The claimed phenotype is amply described.

Applicants submit that the specification sufficiently describes the effect of expression of the LpTFL1 such that one of skill would recognize that Applicants had possession of the claimed method of reducing flowering in a plant. Specifically, the specification discloses that LpTFL1 extends the vegetative-inflorescence phase, increases lateral branching, represses flowering in perennial plants in the first year of growth, and/or represses flowering perennial plants after the first year of growth. (Specification, line 9-13). This phenotype is distinguished from that of TFL1.

This phenotype is supported by additional statements in the Specification. The phenotype of plants over expressing LPTFL1 includes:

Arabidopsis

- vegetative non-flowering Arabidopsis or severely delayed flowering lacking cauliflower-like structures with a high density of trichromes that covered the leaves and the shoot apical meristem. (Specification, page 38, lines 1 - 9).

Rye grass

- expression of LpTFL1 in the apex in the inflorescence and also in leaves and roots and mature flowers (Specification, page 37 lines 22 - 29).
- increased upregulation of LpTFL1 during long day introduction (Specification, page 37 lines 22 - 29).
- Transgenic plants were arrested at the vegetative phase (Specification, page 44, line 11).
- The effect of LpTFL1 overexpression was independent of genotype, though all genotypes responded to transformation (co-transformation efficiency the percentage of non-flowering LpTFL1 overexpressing lines were equally distributed. (Specification, page 44, lines 22-26).

Red Fescue

- only two artificially vernalized transgenic plants flowered (Specification page 49, line23-24)
- while four of the transgenic lines did not flower during the first vernalization, three of those lines also did not flower during the second season, and of the lines that did flower, some produced only one or two flowers. (Specification, page 50, lines 7-10).
- Expression of LpTFL1 in flowering plants may cause a reduction of culm length and leaf width (Specification, page 54, line 7).

Applicants submit that based on this description of the phenotype of LpTFL1 transgenic plants, one of skill would recognize when 1) the plant was successfully transformed with LpTFL, and 2) that the plant had the desired activity. Thus, one of skill would have recognized at the time of filing that Applicants had possession of a genus of nucleotides, which when expressed in a plant would provide that plant with extended vegetative-inflorescence phase, increased lateral

branching, repressed flowering in perennial plants in the first year of growth, and/or repressed flowering perennial plants after the first year of growth.

c. The Existing knowledge in the particular field supports that the invention is amply described.

Plant PEBPs are well known in the art. The specification provides the sequences of 11 additional plant PEBPs. (See figure 5b). Moreover, methods for obtaining sequences having 83% sequence identity to SEQ ID NOs: 1 or 2 and sequences having 83% sequence identity to a nucleotide sequence encoding SEQ ID NO: 3, transforming a plant, and determining when a plant has reduced flowering are also known in the art. Thus, Applicants submit that one of skill would have recognized that Applicants had possession of the claimed genus of sequences at the time of filing.

d. The Examiner did not properly consider the scope of the claims.

Applicants submit that the Examiner has based his analysis on a broader invention than the one currently claimed. The Examiner states that "[t]he Office contends the importance of the YESP(K/R) motif is questionable because TFL1 and CEN do not contain the YESP(K/R) motif and they are homologs of LpTFL1." (Office Action, page 7).[1] It appears that that the Examiner has not based his analysis on the *claimed* invention.

Applicants do not broadly claim all homologs of LpTFL1. The claimed invention requires a specific percent homology, which TFL1 and CEN do not meet. The claimed invention also requires that the YESP(K/R) motif be present. In SEQ ID NO: 3, this sequence is found at amino acids 108-112. The serine residue at amino acid 110 is common to some plant PEBP sequences.

As the Examiner has indicated, neither TFL1 or CEN have a YESP(K/R) motif.

[1] Applicants are concerned that the Examiner is making an assumption that the sequences are homologs. While TFL1 and CEN are known homologs, the other sequences listed in 5b are merely homologous, *i.e.*, have a certain sequence identity. There is no indication that the inventors considered the sequences to have a similar origin.

Furthermore, the Specification suggests that the LpTFL1-like activity, including lateral branching in Arabidopsis which is "more extreme compared with overexpression of TFL1 in Arabidopsis." (Specification, page 4, lines 11-12). Also, LpTFL1-like activity may include repressing flowering after the first year of growth. Such repressors "have not hitherto been identified." (Specification, page 4, lines 14-15). Applicants specifically compared the activities of LpTFL1 and TFL1 in the Specification, pages 32-34 "LpTFL1 Delays or Prevents flowering in Arabidopsis"). While both TFL1 and CEN may be homologs of LpTFL1, they both failed to demonstrate the non-flowering phenotype that lasted over more than one year, which is characteristic of LpTFL1. Based on this data and the fact that there is a significant difference among plant PEBP sequences at position 110 which is shared by other PEBP sequences, it is reasonable to conclude that in combination with the required sequence identity, YESP(K/R) is an essential feature of the present invention.

Therefore, the Examiner's comparison of the TFL1 and CEN to the present invention to conclude that there is inadequate support for the claimed method and transgenic plant is irrelevant. In making this conclusion, the Examiner did not consider the specific requirements of the claims. Accordingly, Applicants request that the Examiner withdraw the rejection.

9. Claim Rejections under 35 U.S.C. § 112, Enablement

The Examiner has rejected claims 65-66, 68-80, 86, 88-100 and 102-105 under 35 U.S.C. § 112, first paragraph as not being enabled by the Specification. Although the Examiner concedes that the Specification is enabled for "SEQ ID NO: 1 or 2 encoding SEQ ID NO: 3 and plant transformation therewith and method of reducing or preventing flowering comprising expressing SEQ ID NO: 1 or 2 or a polynucleotide encoding SEQ ID NO: 3" the Examiner asserts that the Specification "does not reasonably provide enablement for any polynucleotide exhibiting less than 100% sequence identity to SEQ ID NO: 1 or 2 or to a polynucleotide encoding a protein exhibiting less than 100% identity to SEQ ID NO: 3 and plant transformation therewith and

method of reducing or preventing flowering comprising said polynucleotide." (Office Action of March 18, 2009, page 8).[2]

The rejection is in error because the Office failed to establish a *prima facie* case of non-enablement. The legal standards to be applied in assessing enablement are (1) whether the experimentation needed to practice the claimed invention is undue or unreasonable and (2) whether the description discloses sufficient information to enable a person skilled in the art to make and use the claimed invention.

With respect to the first standard, i.e. undue experimentation, the TRAINING MATERIALS FOR EXAMINING PATENT APPLICATIONS WITH RESPECT TO 35 U.S.C. SECTION 112, FIRST PARAGRAPH-ENABLEMENT CHEMICAL/BIOTECHNICAL APPLICATIONS which are given to Examiners cites *In re Wands* (8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as the applicable standard. When applying this standard, the burden is on the Examiner to make a *prima facie* case of non-enablement this is well grounded in scientific reasoning or evidence. See *In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993); See also MPEP §706.03 and §2164.04. As stated in *Wright*, the application must be considered enabling if there is no reason to doubt the truth of the statements made in the patent application. *Wright*, 27 USPQ2d at 1513. In addition, the Board of Patent Appeals and Interferences recently addressed the question of undue experimentation with respect to a claim directed to a nucleic acid and which recited 'percent identity' language, finding that the claims at issue were, indeed, enabled. *Ex parte Kubin*, 83 USPQ2d 1410 (B.P.A.I. 2007). That is, claims containing 'percent identity' language are not inherently non-enabled.

With respect to the second standard, i.e. a skilled artisan's understanding, it is worth repeating that the description in patents is not addressed to the public generally but to those skilled in the

[2] Applicants note that the Examiner in the Office Actions of January 2, 2008 and August 20, 2008 previously rejected claims to a plant comprising a nucleotide having 65% sequence identity SEQ ID NOs: 1-3 under 35 U.S.C. § 102 and §103 over Jensen et al., which Applicants have established is their own work. To be anticipatory or obvious, the prior art must be enabling. Thus, the Examiner has conceded that the invention is enabled. Accordingly, Applicants request that the rejection be withdrawn.

art. This is why a patent need not disclose what is well known in the art. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 USPQ 481, 489 (Fed. Cir. 1984). The sufficiency of a specification must therefore be tested in the light of this fact and judged by what it conveys to those who *are* skilled in the art. *In re Nelson and Shabica*, 126 USPQ 242, 251 (C.C.P.A. 1960). An omission is not fatal where the disclosure is sufficient to enable those skilled in the art to practice the invention. *In re Myers* 161 USPQ 668, 671 (C.C.P.A. 1969).

As described in detail below, Applicants respectfully submit that the Examiner failed to establish a prima facie case of non-enablement because: (1) Application of the *Wands* factors supports the conclusion that the claims are enabled; (2) the Examiner's arguments fail to consider what is known and understood by one skilled in the art and (3) the Examiner has ultimately failed to present an argument that is well grounded in scientific reasoning or evidence.

9.1 Application of the *Wands* factors leads to the conclusion that the claims are enabled.

Applicants respectfully submit that the proper analysis applying the *Wands* factors supports the conclusion that the claims are enabled. As described in the MPEP § 2164.01(a), the *Wands* factors include: a) the breadth of the claims; b) the nature of the invention; c) the state of the prior art; d) the level of ordinary skill in the art; e) the level of predictability in the art; f) the amount of direction provided by the inventor; g) the existence of working examples; and h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *See also, In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). As noted in the MPEP:

> It is improper to conclude that **a disclosure** is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all of the evidence related to each of these factors, and any conclusion of non-enablement must be based on the evidence as a whole.

MPEP § 2164.01(a) (citing *In re Wands*, 8 USPQ2d 1400, 1404 (Fed Cir. 1988); emphasis added). The MPEP further states:

> The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing **all** the above noted factual considerations.

MPEP § 2164.01(a) (emphasis added).

Applicants respectfully submit that the Examiner's analysis, discussed in more detail below, completely fails to weigh the various *Wands* factors and instead focuses only on an alleged lack of guidance by the inventors. As noted in the MPEP, the analysis must be of the disclosure and all of the factual considerations must be weighed.

9.1.1 Disclosure in the Specification

Applicants have pointed to the disclosure of the Specification in section 8.1, above, to show that the written description requirement has been fulfilled, and these same disclosures provide support that the claims are enabled. Because the genomic DNA, cDNA (SEQ ID NO:1 and 2) and amino acid sequences (SEQ ID NO:2) are provided in the Specification, it is straightforward to determine what variations of these nucleotide and amino acid sequences fall with the 83% sequence identity recited in the claims. Applicants have also indicated that conservative amino acid substitutions can be made that result in a silent change (Specification, page 9, line 19 to page 10, line 3). Importantly, Applicants have provided a homology table which indicates that sequences having the required degree of homology come from the same grass family, poacaea. (Table submitted with Amendments of May 1, 2008, December 22, 2008, including accession numbers, and attached here). Applicants have also provided a consensus sequence between the claimed LpTFL1 and other PEBP proteins. (Figure 5b). These additional molecules can be generated according to methods described in the Specification and methods well known in the art, such as those provided on pages 6 and 9-12. References for computer programs for comparing sequence identity of nucleotides and/or amino acids are provided on page 6 and 10-12 of the Specification. Transformation and regeneration protocols are discussed on pages 28-31 (Arabidopsis), 39-41 (perennial ryegrass), and 45-49 (red fescue) of the Specification. Methods

for screening transformed plants for delayed flowering are discussed on pages 9, 28, 40-43 (perennial ryegrass), 45 (red fescue) and the specific protocols for multiple different end points are discussed (such as time to flowering, tissue specific expression of the transgene, number of inflorescences, number of cauline leaves, and axillary meristem development).

Data about and further information to determine the phenotypes of the various transformants showing delayed flowering is discussed above and found in Figures, described on pages 24-27. In particular, figure 5 compares the presently claimed sequences to other PEBPs through a consensus sequence, Figure 6 shows data about the local expression of LpTFL1, figure 7 presents data detailing the delay of the vegetative phase of Arabidopsis transformed with the present invention, figure 8 is a pictoral representation of the effects of transformation with the presently claimed sequences, figure 12 discloses the effects on red fescue, and figure 24 shows the flowering and non-flowering in red fescue transformants after one year (400 days).

Furthermore, the LpTFL1-like activity is explicitly cited in the Specification, as discussed above with the written description rejection. The activity is directly compared to that of TFL1, as discussed above. There is not a requirement that the activity be "quantifiable" as the Examiner seems to require, merely that it be recognizably different compared to the wild-type- *i.e.,* that expression of the claimed sequence extends the vegetative-inflorescence phase, increases lateral branching, represses flowering in perennial plants in the first year of growth, and/or represses flowering perennial plants after the first year of growth. (Specification, page 4, lines 9-15).

This evidence establishes that the Specification teaches in detail how to: 1) make variants of SEQ ID NOs: 1-3; 2) calculate the percent identity between SEQ ID NOs: 1-3 and the variant sequence; 3) transform a plant cell with a nucleotide of interest and regenerate a plant from that cell; and 4) screen the resulting plants to select one having reduced or prevented flowering.

8.1.2. Application of the Wands Factors

Application of the *Wands* factors to these facts supports the conclusion that the claims are enabled. First, the present invention is in the field of molecular biology, which the *Wands* court has already held as having a high level of skill in the art. *Wands*, 8 USPQ2d at 1406. Second, as the citations to the Specification above prove, the Specification provides considerable guidance and direction for producing the claimed nucleotide sequences. Third, as in *Wands*, the methods of making the claimed nucleic acid sequences and screening for activity are known in the art and described in the Specification at the cited passes. *Id.* Fourth, the Specification provides working examples of sequences within the scope of the claims (i.e. SEQ ID NO: 1 and 2). Fifth, given the extensive guidance provided in the Specification (cited above) and the high level of skill in the art, the experimentation involved to produce other sequences within the scope of the claims is well within the skill of those in the art. As held by the *Wands* court "[t]he test is not merely quantitative since a considerable amount of experimentation is permissible, if it is merely routine, or if the Specification in question provides a reasonable amount of guidance with respect to the direction in which the experiment should proceed. *Id.* at 1404.

Turning to claim 65, the scope of the claims must be considered as part of the enablement analysis. MPEP § 2164.04. Independent claim 65 is directed to a method of reducing flowering in a plant comprising transforming a plant cell with a nucleotide sequence encoding an amino acid sequence having at least 83% identity to SEQ ID NOs: 1or 2 or a nucleotide sequence having 83% sequence identity to a nucleotide sequence encoding SEQ ID NO: 3, comprising expressing said nucleotide sequences in a plant.

Applicants note that the Board of Patent Appeals and Interferences addressed the question of undue experimentation with respect to a claim directed to a nucleic acid and which recited 'percent identity' language. *Ex parte Kubin*, 83 USPQ2d 1410 (B.P.A.I. 2007), *aff'd In re Kubin,* 90 U.S.P.Q.2d 1417 (Fed. Cir. 2009). Applying the *Wands* factors the Board specifically commented on the following factors finding that (1) the experimentation involved to produce

other sequences within the scope of the claim and thus to practice the full scope of the claim would have been well within the skill of those in the art and thus would have been routine; (2) methods of making the claimed nucleic acid sequences and screening for activity were known in the art and described in the Specification; (3) the Specification provides two working examples; (4) the relative skill in the art was high and (5) that molecular biology is generally an unpredictable art. *Id.* at 1415, 1416. The Board concluded that while the amount of experimentation might have been extensive, it would have been routine and that the techniques required were well known to those skilled in the art. *Id.* at 1416. In other words, no undue experimentation was needed in order to make and use the claimed sequences and the claims were enabled.

Applicants submit that the disclosure in the Specification that supports claim 65 is also sufficient for enablement. As described above, given the high level of skill in the art, the extensive guidance in the Specification and the methods known in the art, obtaining plants having reduced flowering by expressing a nucleotide sequence encoding an amino acid sequence having at least 83% identity to SEQ ID NO:1 or 2 and to nucleotide sequences having 83% sequence identity to a nucleotides sequence encoding SEQ ID NO: 3, does not require undue experimentation. Thus Applicants respectfully submit that claim 65 is enabled.

9.2. The Examiner's arguments fail to consider what is known and understood by one skilled in the art

One skilled in the art could easily identify all of the nucleotides that encode a polypeptide with at least 83% identity to SEQ ID NO: 3 with the aid of a computer. Furthermore a consensus sequence is provided that gives guidance as to the preferred regions where nucleotide alterations can be made. Despite the Examiner's conclusory statement that "[t]he state of the art is such that one of skill in the art cannot predict which nucleic acids that exhibit less than 100% sequence identity to a nucleic acid encoded by SEQ ID NO: 3 will encode a protein with the same activity as a protein encoded by SEQ ID NO: 1 or 2," absolute prediction is not required. The issue is

whether it would require undue experimentation to determine which sequences have the claimed activity. As discussed above, the experimentation would merely be routine. Consequently, Applicants respectfully submit that the disclosure of the Specification enables claim 65.

9.3. The Examiner has ultimately failed to present an argument that is well grounded in scientific reasoning or evidence

The burden is on the Examiner to make a *prima facie* case of non-enablement that is well grounded in scientific reasoning or evidence. *See In re Wright* USPQ2d 1510 (Fed. Cir. 1993); *See also* MPEP § 706.03 and § 2164.04. Applicants respectfully submit that the Examiner did not make properly reasoned and scientifically supported statements explaining Applicant's alleged failure to comply with 35 USC § 112. As described above, analysis of the teachings of the Specification according to the *Wands* factors supports a conclusion that practice by one skilled in the art of the full scope of the claims does not require undue experimentation. However, instead of considering the language of the claims and the teachings of the Specification in light of the *Wands* factors, the Examiner has focused instead on the alleged lack of data. But as stated above, Applicants have disclosed the results of the experiments employing the claimed method. Furthermore, enablement does not require disclosure of the "absolute predictability" by which a method achieves its results.

In addition, the small amount of scientific evidence presented to support the Examiner's allegation of non-enablement bears little or no relation to the claimed method and/or the nucleic acids used in the method. The Examiner presents evidence of the unpredictability of other amino acid sequences which fall *outside* the claims, such as TFL1 and CEN, thus are not relevant to the claimed sequences.

It is also remarkable that the Examiner focused only on the exceptional examples in the references and/or chose references that discuss the exceptions to well-established methods, thus ignoring the majority of the results and/or the well established principles which do not support

the Examiner's allegations. For example, the Examiner cites two unrelated proteins for the proposition that a single amino acid substitution can change the function of a protein. While that may be the case for that protein family, it is certainly not more likely than not that such a small variation would affect the claimed genus of sequences. Thus the Examiner failed to provide any scientific reasoning or evidence that is specific to the claims at issue or that is supported by the preponderance of the available scientific evidence. Therefore, Applicants respectfully submit that the Examiner did not make a *prima facie* case of enablement. Accordingly, Applicants respectfully request that this ground of rejection be removed.

9.4. The Examiner's arguments fail to consider the limitations of claim 86 and claims 102-105

The facts and analysis above provide even stronger support for concluding that claim 86 is enabled. Dependent claim 86 is directed to the method where the nucleotide sequence encoding an amino acid sequence has at least 95% identity to SEQ ID NOs: 1 or 2 and a nucleotide sequence having 95% sequence identity to a nucleotide sequence encoding SEQ ID NO: 3. That is, claim 86 allows for even fewer changes to be made to the protein as defined by the consensus sequence. Thus, Applicants respectfully submit that claim 86 is enabled.

Moreover, claims 102-105 are directed to making a transgenic plant having 85% sequence identity to the claimed sequences. The Examiner did not reject these claims for written description, but did for enablement. However, methods of making a transgenic plant are well-known in the art. Thus, Applicants submit that claims 102-105 are enabled. Applicants request that the rejection be withdrawn.

9.5 Conclusion of Enablement

In view of the remarks above, the disclosure in the Specification, and the knowledge in the art, Applicants submit that the claims are enabled and request that the rejection be withdrawn.

10. Claim Rejections under 35 U.S.C. § 101, Non-Statutory Subject Matter

The Examiner rejects claims 65-66, 68-72, 74, and 86-93, under 35 U.S.C. § 101, as being drawn to non-statutory subject matter. Applicants have amended the claims to recite a "heterologous" nucleotide. Applicants accordingly submit that said amendment overcomes the Examiner's rejection. Applicants request that the rejection be withdrawn.

11. Claim 101

The Examiner objects to claim 101 as being dependent upon a rejected base claim. Applicants submit that the amendments to the claims and the remarks above fully address the Examiner's concerns about the base claims 65, 73, and 76. Accordingly, Applicants request that the objection to claim 101 be withdrawn and that claim 101 be allowed along with the base claims.

CONCLUSION

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: July 20, 2009

Respectfully submitted,

By

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Attachments: Table of percent homologies- no shading.

Sequence Listing